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09/500,849	02/10/2000	Robert L. Hudkins	CEPH-0939	3140

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EXAMINER

WRIGHT, SONYA N

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 05/07/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/500,849	HUDKINS ET AL.
Examiner	Art Unit	
Sonya Wright	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-94 is/are pending in the application.

4a) Of the above claim(s) 62,66-72 and 75-94 is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-58,60 and 61 is/are rejected.

7) Claim(s) 63, 65, and 74 is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. ____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.

4) Interview Summary (PTO-413) Paper No(s). ____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: ____.

DETAILED ACTION

Claims 1-94 are pending in this application.

Applicant's election with traverse of Formula II in claim 21, wherein Q is NR13 or R7A, and W is CR18R7 in Paper No. 5 filed 3-19-02 is acknowledged. Since Applicants did not give reasons for traverse, the response will be considered as a non-traversal.

The following generic concept is identified for examination along with the elected embodiment: the generic structure for Table 7, page 48, wherein Q is NR13; W is CR18R7; A, B, C, D, E, and F form a 3 to 6 membered ring wherein one of A, B, C, D, and E is oxygen and the others are a bond or CH₂, and all other variables are as defined.

The compositions claims 63, 64 and 65 and the method claims 73 and 74 have also been identified for examination. All other composition and method claims have been restricted out for being drawn to different subject matter. The compound claims 1-58, 60, 61, the composition claims 63, 64, and 65, and the method claims 73 and 74 have been examined commensurate in scope with the generic concept supra.

The remaining subject matter of claims 1-58, 60, 61, 63, 64, 65, 73, and 74 in part and claims 66-72, and 75-94 in their entirety stands withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

The withdrawn subject matter of claims 1-58, 60, 61, 63, 64, 65, 73, and 74 in part and claims 59, 62, 66-72, and 75-94 in their entirety is properly restricted as said subject matter differs in structure and element from the elected subject matter so as to

be patentably distinct therefrom, i.e. a reference which anticipated the elected subject matter would not even render obvious the withdrawn subject matter and fields of search are not co-extensive. Were Applicant to argue that the Groups are not distinct, then there could be no patentability of all the claims over Saulnier et al., WO 98/07433, compound Ib, page 18.

Claims 1-94 are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to the elected subject matter identified supra.

The requirement is still deemed proper and is therefore made **FINAL**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-58, 60, and 61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S.

Patent No. 5,808,060. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the patent claims are both drawn to cyclic substituted fused pyrrolocarbazole compounds, which are useful as inhibitors of protein kinase C. The patent teaches a genus which embraces the genus of the instant claims. The "X" variable in the patent corresponds to the "Q" and "W" variables in the instant claims. The "X" variable in the patent is broader than the definitions of "Q" and "W" in the instant claims. One would be motivated to prepare the instant compounds because the patent compounds are similar in structure and have the same method of use. In the patent see the compound Examples in columns 17, 18, and 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-58, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saulnier et al., WO 98/07433.

Determination of the scope and content of the prior art (MPEP §2141.01)

Saulnier et al. teach indolopyrrolocarbazoles as antitumor agents. Applicant discloses fused pyrrolocarbazoles and isoindolones for use as antitumor agents.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the Saulnier et al. and the instant claims is that Saulnier et al. generically teach "CH₂" for the "W" variable in the instant claims. See Saulnier et al., page 18, compound Ib, and the Q variables in Table V on pages 60-62.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would be motivated to prepare a compound wherein W is CR18R7 in the claims **because** Saulnier et al. generically teach that the "W" moiety can optionally be O, S, or CH2. Variation of the "W" moiety has been exemplified to have similar activity, see Table V in the instant claims. It would be expected by a person having ordinary skill in the art that the other options generically taught by Saulnier et al. would have similar activity.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 64 and 73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (*In re Wands*, 8 USPQ2d 1400, 1404 (CaAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claims 64 and 73 are directed to "preventing prostate disorders". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There are a vast number of prostate related disorders Applicant does not give support for "preventing" all forms of these disorders. The art pertaining to prostate disorders remains highly unpredictable. The various forms of these disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Applicant gives limited examples which do not enable the full scope of this claim. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

It is suggested that applicants delete "preventing" from claims 64 and 73 in order to obviate the rejection under 35 U.S.C. 112 first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation rings B and F are selected from . . . (b) an unsaturated 5-membered carbocyclic aromatic ring, and the claim also recites rings B and F are selected from . . . (c) an unsaturated 5-membered carbocyclic aromatic ring in which either 1). . . 2) . . . or 3). . . which is the narrower statement of the range/limitation.

On page 94, line 5, Applicant states that ring J contain at least one carbon atom that is saturated. However, Grant & Hackh's Chemical Dictionary Fifth Edition (1969) defines "saturated" as "an organic compound with neither double nor triple bonds". Carbon bonds, not atoms are saturated, as indicated in the claim. Correction is suggested. Applicants should note that any correction should be supported by the specification.

Claim 41 recites the limitation "Table 8 supra". There is insufficient antecedent basis for this limitation in the claim because Table 8 is not included in the claims. Correction is suggested.

Claim Objections

Claim 42 is objected to because of the following informalities: Claims must be one sentence. Therefore, in line 8, the brackets and the subject matter in the brackets should be deleted. Appropriate correction is required.

Claims 63, 65, and 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for

draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Celia Chang

Primary Examiner

Group 1600

Sonya Wright

May 6, 2002